Remarks

Amendments to the claims

Claims 1-9 and 29-80 are pending. Claims 1-9 and 29-80 were rejected. Claim 31 is amended to depend on claim 29 instead of claim 27. Claim 33 is amended to correct an inadvertent error. Claim 39 is amended to correct a typo. New claims 81-135 are added. New claims 81-103 specifies an ingestible device of claim 29 including additional features defined therein. New claims 104-106 specify methods for charging and operating ingestible devices including the three main types of spring described in the specification. New claims 107-135 eliminate the multiple dependencies of claims 56, 65, 77, 78, and any claims dependent thereon. Support for the new claims 81-103 is found in, for example, the description of the springs on pages 17, 18, 19, 25, 30 to 36 and 38; and in the effect of the springs described on page 23. Support for new claims 104-106 is found at, for example, p. 32, line 24 to p. 36, line 29.

Rejections under 35 U.S.C. 102(b)

Claims 1, 3, 29, 33, 39, 42, 50, 69 and 80 were rejected as anticipated by U.S. Patent Nos. 5,167,626 to Casper et al. ("Casper"); 5,279,607 to Schentag, et al. ("Schentag"); and 5,217,449 to Yuda, et al. ("Yuda"). The applicants respectfully traverse the rejections.

The claimed invention

Claims 1-9 and 29-80 are drawn to an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal and the method of using the device. The device includes: (1) an openable reservoir, for the substance, that is sealable against leakage of the substance; (2) an actuator mechanism for opening the reservoir; (3) an energy source, operatively connected for powering the actuator mechanism; (4) a

releasable latch for controllably switching the application of power to the actuator from the energy source; and (5) a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the receiver including an air core having coiled therearound a wire, characterized in that the coiled wire lies on or is embedded in an outer wall of the device. In the alternative, the device includes: (1) an openable reservoir, for the substance, that is sealable against leakage of the substance; (2) an actuator mechanism for opening the reservoir; (3) an energy source, operatively connected for powering the actuator mechanism; (4) a releasable latch for controllably switching the application of power to the actuator from the energy source; and (5) a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the device including a ferrite core having coiled therearound a wire for coupling received electromagnetic radiation to the releasable latch, characterized in that the device comprises an elongate, hollow housing, the ferrite core being elongate with its longitudinal axis aligned with the longitudinal axis of the hollow housing.

Casper

Casper describes a medical capsule device for releasing a substance at a defined location in the gastrointestinal tract. The device has a capsule body having one or more apertures in the circumferential wall thereof and a sleeve valve rotatably positioned therein having one or more corresponding apertures in the circumferential wall thereof. The sleeve valve includes a coil and electrically connected heatable resistor which are operatively associated with an actuator member formed of a shape memory alloy responsive to heat and which will move from a non-heated first shape to a heated second shape. Actuator stop means are provided in the capsule

body for being engaged by the actuator member during movement from the non-heated first shape to the heated second shape so that the actuator member movement will serve to rotate the sleeve valve to an open position (col. 3, line 46 to col. 4, line 32).

Casper, however, does not disclose an air core as defined in claim 1, the longitudinal axis of the ferrite core being aligned with the longitudinal axis of the housing of the ingestible device as defined in claim 3, or the method as defined in claim 29, particularly the steps of simultaneously inhibiting the generation of long wavelength radio waves and short wavelength electrostatic radiation in the vicinity of the abdomen of the user. Besides, Casper fails to disclose a transmitter as defined in claim 33 or claim 69, any kind of spring recited in claims 39, 42 and 50.

Accordingly, Casper does not anticipate claims 1, 3, 29, 33, 39, 42, 50, 69 and 80 and new claims 81-106 under 35 U.S.C. 102(b).

Schentag

Schentag describes an ingestible capsule and process for delivery, particularly repeatable delivery, of a medicament to the alimentary canal. The capsule contains an electric energy emitting means, a radio signal transmitting means, a medicament storage means and a remote actuatable medicament releasing means. The capsule signals a remote receiver as it progresses through the alimentary tract in a previously mapped route and upon reaching a specified site is remotely triggered to release a dosage of medicament (col. 2, line 64 to col. 3, line 62).

Schentag does not disclose an air core as defined in claim 1, the longitudinal axis of the ferrite core being aligned with the longitudinal axis of the housing of the ingestible device as defined in claim 3, or the method as defined in claim 29, particularly the steps of simultaneously

inhibiting the generation of long wavelength radio waves and short wavelength electrostatic radiation in the vicinity of the abdomen of the user. Nor does it teach any kind of spring recited in claims 39, 42 and 50.

With regard to claim 33, Schentag discloses a restraint in the form of glue spot 44, which retains a diaphragm 45 in a high potential energy state until energisation of a circuit to cause melting of the glue spot and release of the diaphragm. The diaphragm then pushes a rupture pin 46 which expels a substance from a reservoir. At the same time the rupture pin 46 engages a trip wire 17 that changes the resonant frequency of a transmitter circuit.

However, column 6, lines 3 to 13 of Schentag clearly specifies:

> "Transmitter 40 operates **independently** of actuator 41 and is designed to emit a detectable radio signal, from transmission core 38, upon completion of the circuit by removal of lockout 36. The radio signal may be constant or can be intermittent, but should be of sufficient intensity to be detectable through an antenna located outside of the body, by a receiver. Generally, a non-modulated signal, outside the broadcast range, is preferred. Typically **there is no provision for switching off transmitter 40 and it remains a transmitting mode throughout passage of the capsule through the alimentary tract**."

It follows therefore that there is no "restraint operable to limit operation of the actuator mechanism" that "on release of the latch ... operates a switch to activate the transmitter for transmission of a said signal", as claimed in claim 33.

This difference between the device defined by claim 33 and the Schentag device is further reinforced by the presence in the Schentag device of the lockout 36. This component of the Schentag device must be removed before swallowing of the device, otherwise it would present an alimentary tract blockage or a choking hazard. The lockout 36 is the switch that switches on the transmitting circuit of the Schentag device.

Accordingly, Schentag does not anticipate claims 1, 3, 29, 33, 39, 42, 50, 69 and 80 and new claims 81-106 under 35 U.S.C. 102(b).

Yuda

Yuda describes a medical capsule having an outer cylinder and a piston movable in the outer cylinder, the piston being activated by an externally given signal so as to discharge a medicine to the outside of the capsule or to suck a humor for a sampling purpose, as well as an apparatus for activating this medical capsule. The capsule has a remote-controllable means including a normally-opened lead switch which connects a power supply to an activating means in response to an externally given magnetic signal thereby initiating activation of the medical capsule, whereby a simple medical capsule

The Yuda arrangement relies on the generation of a magnetic field using generator apparatus as shown in Figures 4 and 5 in order to operate a magnetic lead switch shown in Figure 2. The lead switch connects a battery B to a heater filament 16. Heating of the heater filament fuses a fixing thread 28 and allows a piston 5 to move under the influence of a coiled spring 26 to expel e.g. a medicine dose from a chamber A.

Therefore, Yuda does not disclose or teach the coil as specified e.g. in claims 1 and 3, the lead switch of Yuda being entirely magentomotive.

Further, as is clearly explained in column 6, lines 49 to 68 of Yuda, the lead switch s requires a constant, aligned magnetic force to operate. This follows from the absence of a coupling coil as defined in claim 1 and claim 3. Therefore, to one of ordinary skill in the art, Yuda does not anticipate claim 29, which calls for the generation of an oscillating magnetic field.

In addition, Yuda contains no means for signaling release of a medicament or other

substance. Therefore, Yuda does not disclose a restraint that also operates as a switch to activate a transmitter for transmission of a signal indicative of operation of the device. Accordingly, claim 33 of the application is novel over Yuda.

Claims 39, 42, and 50 require special spring arrangements as defined therein. In contrast, Yuda is entirely drawn to using conventional springs for powering its piston. Therefore, Yuda does not disclose claims 39, 42 and 50, and new claims 100-102.

Yuda does not disclose a restraint that doubles as a switch for activating a transmitter mechanism as defined in claim 69. Therefore, Yuda does not disclose claim 69.

Accordingly, Yuda does not anticipate claims 1, 3, 29, 33, 39, 42, 50, 69 and 80 and new claims 81-106 under 35 U.S.C. 102(b).

Rejections under 35 U.S.C. 103

Claims 2, 4-9, 30-32, 34-38, 40-41, 43-49, 51-68 and 70-79 were rejected as obvious under 35 U.S.C. 103 over Casper, Schentag and/or Yuda. The applicants respectfully traverse the rejection.

Claims 2, 4-9, 30-32, 34-38, 40-41, 43-49, 51-68 and 70-79 are dependent claims, depending on independent claims 1, 3, 29, 33, 39, 42, 50, 69, respectively. As discussed above, Casper and Schentag, alone or combined, fail to disclose an air core as defined in claim 1, the longitudinal axis of the ferrite core being aligned with the longitudinal axis of the housing of the ingestible device as defined in claim 3, the method as defined in claim 29, particularly the steps of simultaneously inhibiting the generation of long wavelength radio waves and short wavelength electrostatic radiation in the vicinity of the abdomen of the user, or any kind of spring recited in claims 39, 42 and 50. In addition, Casper fails to disclose a transmitter as

defined in claim 33 or claim 69, and Schentag does not disclose restraint operable to limit operation of the actuator mechanism as required in claim 33 and 69. Similarly, Yuda fails to disclose the coil as recited in claims 1 or 3, the oscillating magnetic field of claim 29, the restraint that operates as a switch to activate a transmitter for transmission of a signal indicative of operation of the device as defined in claim 33, the special spring arrangements defined in claim 39, 42 and 52, and the restraint that doubles as a switch for activating a transmitter mechanism as required in claim 69. Therefore, Casper, Schentag, and Yuda, alone or combined, fail to disclose independent claims 1, 3, 29, 33, 39, 42, 50 and 69 and claim 80, which dependent on claim 29. Claims 2, 4-9, 30-32, 34-38, 40-41, 43-49, 51-68 and 70-79 require further limitations as compared to their respective independent claims. Therefore, Casper, Schentag, and Yuda, alone or combined, failed to disclose claims 2, 4-9, 30-32, 34-38, 40-41, 43-49, 51-68 and 70-79. Besides, each of the independent claims of the application defines features that give rise to advantages that were not predictable in the prior art. Overall the devices and methods of the invention offer greatly superior performance over the prior art devices (see p. 27, line 16 and Figure 10). Therefore, one of ordinary skill in the relevant art would not derive the features now claimed in the independent claims from the teachings of Casper, Schentag, and Yuda, alone or combined. Nor could one of ordinary skill in the art derive the features claimed in the dependent claims. Therefore, Casper, Schentag, and Yuda, alone or combined, would not render claims 2, 4-9, 30-32, 34-38, 40-41, 43-49, 51-68 and 70-79 and new claims 81-106 obvious under 35 U.S.C. 103.

Allowance of claims 36-44 is earnestly solicited. A copy of the claims as pending are attached as appendix for the convenience of the Examiner.

Allowance of claims 16-19 is therefore earnestly solicited.

Respectfully submitted,

Zhaoyang Li
Reg. No. 46,872

Date: March 31, 2003

HOLLAND & KNIGHT LLP
2000 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
404-817-8473
404-817-8588 (Fax)

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this Amendment and any documents referred to as attached therein are being facsimile transmitted on this date, March 31, 2003, to Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Peggy Bailey

Peggy Bailey

Date: March 31, 2003

Appendix I. Marked-up Copy of Amended Claims

1. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the receiver including an air core having coiled therearound a wire; characterised in that the coiled wire lies on or is embedded in an outer wall of the device.

2. A device according to Claim 1 wherein the diameter of the coils of the wire is in the range 8-12mm and its length is in the range 10-20mm.

3. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects

radiation within a predetermined characteristic range, the device including a ferrite core having coiled therearound a wire for coupling received electromagnetic radiation to the releasable latch, characterised in that the device comprises an elongate, hollow housing, the ferrite core being elongate with its longitudinal axis aligned with the longitudinal axis of the hollow housing.

4. A device according to Claim 1, wherein the receiver includes the said ferrite core and coil.

5. A device according to Claim 3, wherein the receiver includes the said ferrite core and coil.

6. A device according to Claim 1, wherein the air core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

7. A device according to Claim 3, wherein the ferrite core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

8. A device according to Claim 1, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

9. A device according to Claim 3, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

29. A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, causing a mammal to ingest an ingestible device comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; the receiver being capable of extracting energy from an oscillating magnetic field and the method comprising:

at a chosen time, generating at least one axial, oscillating magnetic field and directing the field at the abdomen of the mammal whereby the receiver intercepts the said field and triggers the latch to cause opening of the reservoir; and

simultaneously inhibiting the generation of long wave radio waves and short wave electrostatic radiation in the vicinity of the said abdomen.

30. A method according to Claim 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed.

31. (amended) A method according to Claim [27] 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed and including the step of generating three said fields, wherein the axes of the said fields are mutually orthogonal.

32. A method according to Claim 29 wherein the or each said field is generated using a coil pair operatively connected to a source of an oscillating current.

33. (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device,

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein:

(i) the latch is thermally actuated;

(ii) the energy source is held in a potential energy state [by the latch] until the latch operates; and

(iii) the device includes a heater for heating the latch whereby, on the receiver detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that:

the device also includes a restraint operable to limit operation of the actuator mechanism; and in that, on release of the latch, the restraint operates a switch to activate the transmitter for transmission of a said signal.

34. A device according to Claim 33 wherein:

the actuator mechanism includes a moveable member moveable under power of kinetic energy from the energy source to promote expulsion of the substance from the reservoir;

the restraint includes a flexible member interconnecting the moveable member and an

anchorage fixed relative to the remainder of the device; and

the switch includes a breakable, electrically conductive member, the flexible member and the breakable member being mutually engageable whereby on movement of the moveable member sufficiently partly or completely to expel or initiate expulsion of the substance from the reservoir the flexible member engages and breaks the breakable member to operate the switch.

35. A device according to Claim 33 wherein the actuator mechanism includes a piston moveable under power from the energy source for compressing the substance in the reservoir to promote its expulsion therefrom.

36. A device according to Claim 33 wherein the transmitter includes a resonant circuit connectable to draw power from the receiver; and the breakable member is an electrical short that electrically isolates the resonant circuit from the receiver until the flexible member breaks the breakable member.

37. A device according to Claim 33 wherein the length of the flexible member is such as to limit the travel of the moveable member to a chosen maximum.

38. A device according to Claim 33 wherein the restraint and the switch are so dimensioned and/or located that the restraint operates the switch at a time corresponding to a predetermined amount of movement of the moveable member.

39. (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of [actring] acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring, in its uncompressed state, has a minimum helical angle of 15°.

40. A device according to Claim 39 wherein the spring includes a wire whose diameter is approximately 0.8mm.

41. A device according to Claim 39 wherein the spring defines a hollow cylinder.

42. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of

which causes operation of the actuator mechanism, characterised in that the spring includes a pair of wires each coiled in loops to define a pair of hollow cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

43. A device according to Claim 42 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa.*

44. A device according to Claim 43 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

45. A device according to Claims 42 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross section.

46. A device according to Claim 42 wherein at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

47. A device according to Claim 42 wherein the ends of the wires defining each said wire are flush with the adjacent loops thereof.

48. A device according to Claim 42 wherein the compressed length of the spring is approximately ⅓ of its length in the uncompressed condition.

49. A device according to Claim 42 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

50. An ingestible device for delivering a substance to a chosen or identifiable location

in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring comprises a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

51. A device according to Claim 50 wherein the waves of each disc radiate generally from its centre.

52. A device according to Claim 50 wherein each disc is an annulus.

53. A device according to Claim 50 wherein each disc is an annulus and wherein each annulus is about 0.25mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

54. A device according to Claim 50 wherein each disc is an annulus and wherein the spring includes 16 said annuli secured together at the respective peaks and troughs of the waves.

55. A device according to Claim 50 wherein each disc is an annulus and wherein the

outer diameter of each annulus is about 8.5mm and the inner diameter is about 4.5mm.

56. (amended) A device according to [any of] Claim[s] 39[, 42 or 50] wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

the device.

57. A device according to Claim 56 wherein the spring encircles one or more further components of the device.

58. A device according to Claim 1 including a retainer for retaining moveable components within the device.

59. A device according to Claim 3 including a retainer for retaining moveable components within the device.

60. A device according to Claim 29 including a retainer for retaining moveable components within the device.

61. A device according to Claim 33 including a retainer for retaining moveable components within the device.

62. A device according to Claim 39 including a retainer for retaining moveable components within the device.

63. A device according to Claim 42 including a retainer for retaining moveable components within the device.

64. A device according to Claim 50 including a retainer for retaining moveable

components within the device.

65. (amended) A device according to [any of] Claim[s] 59 [to 64] wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

66. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

67. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

68. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

69. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising:

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation

of the device;

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein

(i) the latch is thermally actuated;

(ii) the energy source is held in a potential energy state by the latch until the latch operates; and

(iii) the device includes a heater for heating the latch whereby, on the receiver-detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that the device also includes

(a) a restraint operable to limit operation of the actuator mechanism;

(b) a switch for switchably operating the transmitter; and

(c) a switch member operatively interconnecting the actuator mechanism and the switch such that operation of the actuator mechanism causes the switch member to operate the said switch.

70. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch.

71. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch

member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement.

72. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire.

73. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb.

74. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb and wherein the pcb includes one or more perforations in the vicinity of each said resistor track.

75. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the

moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire; wherein a projection protrudes from an edge of a perforation through the pcb; and wherein the latch includes a sharp melting point filament interconnecting the actuator member and the said projection.

76. A device according to Claim 75 wherein the heater is secured to the projection in heat transmitting proximity to the sharp melting point filament.

77. (amended) A device according to [any of] Claim[s] 1, [3, 29, 33, 39, 42, 50 or 69] the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

78. (amended) A device according to [any of] Claim[s] 1, [3, 29, 33, 39, 42, 50 or 69,] including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

79. A method according to Claim 29, including the step of indicating the location of the device in the GI tract of the mammal, using a radioisotope tag.

80. A method according to Claim 29, including the step of indicating the location of

the device in the GI tract of the mammal, using a radioisotope tag and wherein the step of indicating the location includes using Gamma scintigraphy to indicate the location of the device in the said GI tract.

Please add new claims 81-135:

81. (new) A method according to Claim 29, wherein the energy source includes an initially compressed, helical spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring having, in its uncompressed state, a minimum helical angle of 15°.

82. (new) A method according to Claim 81 wherein the spring includes a wire whose diameter is approximately 0.8 mm.

83. (new) A method according to Claim 81 wherein the spring defines a hollow cylinder.

84. (new) A method according to Claim 29 wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

85. (new) A method according to Claim 84 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa*.

86. (new) A method according to Claim 84 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

87. (new) A method according to Claim 84 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross-section.

88. (new) A method according to Claim 84 wherein the at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

89. (new) A method according to Claim 84 wherein the ends of the wires defining each said cylinder-like shape are flush with the adjacent loops thereof.

90. (new) A method according to Claim 84 wherein the compressed length of the spring is approximately one-third of its length in the uncompressed condition.

91. (new) A method according to Claim 84 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

92. (new) A method according to Claim 29, wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a stack of resiliently deformable discs, the periphery of

each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

93. (new) A method according to Claim 92 wherein the waves of each disc radiate generally from its centre.

94. (new) A method according to Claim 92 wherein each disc is an annulus.

95. (new) A method according to Claim 92 wherein each disc is an annulus and each annulus is about .25 mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

96. (new) A method according to Claim 92 wherein each disc is an annulus and the spring includes sixteen said annuli secured together at the respective peaks and troughs of the waves.

97. (new) A method according to Claim 92 wherein each disc is an annulus the outer diameter of which is about 8.5 mm and the inner diameter of which is about 4.5 mm.

98. (new) A method according to Claim 81 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

99. (new) A method according to Claim 84 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or

indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

100. (new) A method according to Claim 92 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

101. (new) A method according to Claim 98 wherein the spring, in use, encircles one or more further components of the device.

102. (new) A method according to Claim 99 wherein the spring, in use, encircles one or more further components of the device.

103. (new) A method according to Claim 100 wherein the spring, in use, encircles one or more further components of the device.

104. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is

initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a helical spring defining the said energy source and having, in its uncompressed state, a minimum helical angle of 15°.

105. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir

via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

106. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves

of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

107. (new) A device according to Claim 42 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

108. (new) A device according to Claim 50 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

109. (new) A device according to Claim 103 wherein the spring encircles one or more further components of the device.

110. (new) A device according to Claim 104 wherein the spring encircles one or more further components of the device.

111. (new) A device according to Claim 60 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

112. (new) A device according to Claim 61 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

113. (new) A device according to Claim 62 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening

therein.

114. (new) A device according to Claim 63 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

115. (new) A device according to Claim 64 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

116. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

117. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

118. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

119. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

120. (new). A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

121. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross

section of the lip is generally parallel sided.

122. (new) A device according to Claim 3, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

123. (new) A device according to Claim 29, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

124. (new) A device according to Claim 33, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

125. (new) A device according to Claim 39, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

126. (new) A device according to Claim 42, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

127. (new) A device according to Claim 50, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

128. (new) A device according to Claim 69, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

129. (new) A device according to Claim 3, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

130. (new) A device according to Claim 29, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

131. (new) A device according to Claim 33, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

132. (new) A device according to Claim 39, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

133. (new) A device according to Claim 42, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

134. (new) A device according to Claim 50, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

135. (new) A device according to Claim 69, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

Appendix II. Clean Version of Amended Claims

1. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the receiver including an air core having coiled therearound a wire; characterised in that the coiled wire lies on or is embedded in an outer wall of the device.

2. A device according to Claim 1 wherein the diameter of the coils of the wire is in the range 8-12mm and its length is in the range 10-20mm.

3. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects

radiation within a predetermined characteristic range, the device including a ferrite core having coiled therearound a wire for coupling received electromagnetic radiation to the releasable latch, characterised in that the device comprises an elongate, hollow housing, the ferrite core being elongate with its longitudinal axis aligned with the longitudinal axis of the hollow housing.

4. A device according to Claim 1, wherein the receiver includes the said ferrite core and coil.

5. A device according to Claim 3, wherein the receiver includes the said ferrite core and coil.

6. A device according to Claim 1, wherein the air core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

7. A device according to Claim 3, wherein the ferrite core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

8. A device according to Claim 1, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

9. A device according to Claim 3, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

29. A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, causing a mammal to ingest an ingestible device comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; the receiver being capable of extracting energy from an oscillating magnetic field and the method comprising:

at a chosen time, generating at least one axial, oscillating magnetic field and directing the field at the abdomen of the mammal whereby the receiver intercepts the said field and triggers the latch to cause opening of the reservoir; and

simultaneously inhibiting the generation of long wave radio waves and short wave electrostatic radiation in the vicinity of the said abdomen.

30. A method according to Claim 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed.

31. A method according to Claim 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed and including the step of generating three said fields, wherein the axes of the said fields are mutually orthogonal.

32. A method according to Claim 29 wherein the or each said field is generated using a coil pair operatively connected to a source of an oscillating current.

33. (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device,

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein:

(i) the latch is thermally actuated;

(ii) the energy source is held in a potential energy state until the latch operates; and

(iii) the device includes a heater for heating the latch whereby, on the receiver detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that:

the device also includes a restraint operable to limit operation of the actuator mechanism; and in that, on release of the latch, the restraint operates a switch to activate the transmitter for transmission of a said signal.

34. A device according to Claim 33 wherein:

the actuator mechanism includes a moveable member moveable under power of kinetic energy from the energy source to promote expulsion of the substance from the reservoir;

the restraint includes a flexible member interconnecting the moveable member and an anchorage fixed relative to the remainder of the device; and

the switch includes a breakable, electrically conductive member, the flexible member and the breakable member being mutually engageable whereby on movement of the moveable member sufficiently partly or completely to expel or initiate expulsion of the substance from the reservoir the flexible member engages and breaks the breakable member to operate the switch.

35. A device according to Claim 33 wherein the actuator mechanism includes a piston moveable under power from the energy source for compressing the substance in the reservoir to promote its expulsion therefrom.

36. A device according to Claim 33 wherein the transmitter includes a resonant circuit connectable to draw power from the receiver; and the breakable member is an electrical short that electrically isolates the resonant circuit from the receiver until the flexible member breaks the breakable member.

37. A device according to Claim 33 wherein the length of the flexible member is such as to limit the travel of the moveable member to a chosen maximum.

38. A device according to Claim 33 wherein the restraint and the switch are so dimensioned and/or located that the restraint operates the switch at a time corresponding to a predetermined amount of movement of the moveable member.

39 (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from

the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring, in its uncompressed state, has a minimum helical angle of 15°.

40. A device according to Claim 39 wherein the spring includes a wire whose diameter is approximately 0.8mm.

41. A device according to Claim 39 wherein the spring defines a hollow cylinder.

42. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring includes a

pair of wires each coiled in loops to define a pair of hollow cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

43. A device according to Claim 42 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa.*

44. A device according to Claim 43 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

45. A device according to Claims 42 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross section.

46. A device according to Claim 42 wherein at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

47. A device according to Claim 42 wherein the ends of the wires defining each said wire are flush with the adjacent loops thereof.

48. A device according to Claim 42 wherein the compressed length of the spring is approximately ⅓ of its length in the uncompressed condition.

49. A device according to Claim 42 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

50. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring comprises a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

51. A device according to Claim 50 wherein the waves of each disc radiate generally from its centre.

52. A device according to Claim 50 wherein each disc is an annulus.

53. A device according to Claim 50 wherein each disc is an annulus and wherein each annulus is about 0.25mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

54. A device according to Claim 50 wherein each disc is an annulus and wherein the spring includes 16 said annuli secured together at the respective peaks and troughs of the waves.

55. A device according to Claim 50 wherein each disc is an annulus and wherein the outer diameter of each annulus is about 8.5mm and the inner diameter is about 4.5mm.

56. (amended) A device according to Claim 39 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

the device.

57. A device according to Claim 56 wherein the spring encircles one or more further components of the device.

58. A device according to Claim 1 including a retainer for retaining moveable components within the device.

59. A device according to Claim 3 including a retainer for retaining moveable components within the device.

60. A device according to Claim 29 including a retainer for retaining moveable components within the device.

61. A device according to Claim 33 including a retainer for retaining moveable components within the device.

62. A device according to Claim 39 including a retainer for retaining moveable components within the device.

63. A device according to Claim 42 including a retainer for retaining moveable components within the device.

64. A device according to Claim 50 including a retainer for retaining moveable components within the device.

65. (amended) A device according to Claim 59 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

66. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

67. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

68. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

69. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising:

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device;

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein

(i) the latch is thermally actuated;

(ii) the energy source is held in a potential energy state by the latch until the latch operates; and

(iii) the device includes a heater for heating the latch whereby, on the receiver-detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that the device also includes

(a) a restraint operable to limit operation of the actuator mechanism;

(b) a switch for switchably operating the transmitter; and

(c) a switch member operatively interconnecting the actuator mechanism and the switch such that operation of the actuator mechanism causes the switch member to operate the said switch.

70. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch.

71. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible

member the slackness of which provides the said lost motion arrangement.

72. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire.

73. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb.

74. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb and wherein the pcb includes one or more perforations in the vicinity of each said resistor track.

75. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch

member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire; wherein a projection protrudes from an edge of a perforation through the pcb; and wherein the latch includes a sharp melting point filament interconnecting the actuator member and the said projection.

76. A device according to Claim 75 wherein the heater is secured to the projection in heat transmitting proximity to the sharp melting point filament.

77. (amended) A device according to Claim 1, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

78. (amended) A device according to Claim 1, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

79. A method according to Claim 29, including the step of indicating the location of the device in the GI tract of the mammal, using a radioisotope tag.

80. A method according to Claim 29, including the step of indicating the location of the device in the GI tract of the mammal, using a radioisotope tag and wherein the step of indicating the location includes using Gamma scintigraphy to indicate the location of the device

in the said GI tract.

81. (new) A method according to Claim 29, wherein the energy source includes an initially compressed, helical spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring having, in its uncompressed state, a minimum helical angle of 15°.

82. (new) A method according to Claim 81 wherein the spring includes a wire whose diameter is approximately 0.8 mm.

83. (new) A method according to Claim 81 wherein the spring defines a hollow cylinder.

84. (new) A method according to Claim 29 wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

85. (new) A method according to Claim 84 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa*.

86. (new) A method according to Claim 84 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

87. (new) A method according to Claim 84 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross-section.

88. (new) A method according to Claim 84 wherein the at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

89. (new) A method according to Claim 84 wherein the ends of the wires defining each said cylinder-like shape are flush with the adjacent loops thereof.

90. (new) A method according to Claim 84 wherein the compressed length of the spring is approximately one-third of its length in the uncompressed condition.

91. (new) A method according to Claim 84 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

92. (new) A method according to Claim 29, wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

93. (new) A method according to Claim 92 wherein the waves of each disc radiate generally from its centre.

94 (new) A method according to Claim 92 wherein each disc is an annulus.

95. (new) A method according to Claim 92 wherein each disc is an annulus and each annulus is about .25 mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

96. (new) A method according to Claim 92 wherein each disc is an annulus and the spring includes sixteen said annuli secured together at the respective peaks and troughs of the waves.

97. (new) A method according to Claim 92 wherein each disc is an annulus the outer diameter of which is about 8.5 mm and the inner diameter of which is about 4.5 mm.

98. (new) A method according to Claim 81 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

99. (new) A method according to Claim 84 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

100. (new) A method according to Claim 92 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or

indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

101. (new) A method according to Claim 98 wherein the spring, in use, encircles one or more further components of the device.

102. (new) A method according to Claim 99 wherein the spring, in use, encircles one or more further components of the device.

103. (new) A method according to Claim 100 wherein the spring, in use, encircles one or more further components of the device.

104. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir

via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a helical spring defining the said energy source and having, in its uncompressed state, a minimum helical angle of 15°.

105. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

106. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

107. (new) A device according to Claim 42 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with

the piston and secured at its other end to a member fixed relative to the remainder of the device.

108. (new) A device according to Claim 50 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

109. (new) A device according to Claim 103 wherein the spring encircles one or more further components of the device.

110. (new) A device according to Claim 104 wherein the spring encircles one or more further components of the device.

111. (new) A device according to Claim 60 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

112. (new) A device according to Claim 61 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

113. (new) A device according to Claim 62 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

114. (new) A device according to Claim 63 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

115. (new) A device according to Claim 64 wherein the retainer includes a rib that

reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

116. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

117. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

118. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

119. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

A2

120. (new). A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

121. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

122. (new) A device according to Claim 3, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

123. (new) A device according to Claim 29, the reservoir of which includes a charge of

liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

124. (new) A device according to Claim 33, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

125. (new) A device according to Claim 39, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

126. (new) A device according to Claim 42, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

127. (new) A device according to Claim 50, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

128. (new) A device according to Claim 69, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

129. (new) A device according to Claim 3, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

130. (new) A device according to Claim 29, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

131. (new) A device according to Claim 33, including a radioisotope tag generating

radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

132. (new) A device according to Claim 39, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

133. (new) A device according to Claim 42, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

134. (new) A device according to Claim 50, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

135. (new) A device according to Claim 69, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.